July 8, 2021

VIA UPS EXPRESS MAIL

Albert Lai, MD
Director
The Regen Centers
71780 San Jacinto Drive, Building D
Rancho Mirage, CA 92270

Dear Dr. Lai:

The Office of Compliance and Biologics Quality in the Center for Biologics Evaluation and Research (CBER) of the United States Food and Drug Administration (FDA) has reviewed the website available at www.theregendoc.com.

On your website, you market cellular products derived from human umbilical cord blood, umbilical cord tissue, amniotic membrane, or adipose tissue, which you refer to as "regenerative medicine therapy," to treat various diseases or conditions, such as chronic obstructive pulmonary disease, leukemia, diabetes, heart failure, and lung and kidney diseases and disorders.

For example, your website states: "Regenerative Medicine treatment is effective to treat issues associated with many diseases and conditions. These are some of the most common problems for which we use stem cell injections . . . Autoimmune diseases such as rheumatoid arthritis, lupus, psoriasis and Lyme disease[;] Neurological diseases such as ALS, multiple sclerosis, dementia, stroke, Parkinson's disease and Alzheimer's disease[;] . . . Failure of the heart, lung, kidneys and other organs[;] Chronic obstructive pulmonary disease (COPD)[;] Diabetes[;] Erectile dysfunction[;] Fibromyalgia."

Your cellular products, appear to be human cells, tissues, or cellular or tissue-based products (HCT/Ps) as defined in 21 CFR 1271.3(d) that would be subject to regulation under 21 CFR Part 1271, issued under the authority of section 361 of the Public Health Service Act (PHS Act) [42 U.S.C. 264].

HCT/Ps that do not meet all the criteria in 21 CFR 1271.10(a), and when no exception in 21 CFR 1271.15 applies, are not regulated solely under section 361 of the PHS Act [42 U.S.C. 264] and the regulations in 21 CFR Part 1271. Such products are regulated as drugs, devices, and/or biological products under the Federal Food, Drug, and Cosmetic Act (FD&C Act) and/or the PHS Act, and are subject to additional regulation, including appropriate premarket review.

Based on the review of your website and other sources, it appears that you do not qualify for an exception in 21 CFR 1271.15, and that your cellular products are intended for nonhomologous uses. Additionally, it appears these products fail to meet other criteria in 21 CFR 1271.10(a). Accordingly, it appears that the products would be regulated as drugs as defined in section 201(g) of the FD&C Act [21 U.S.C. 321(g)] and biological products as defined in section 351(i) of the PHS Act [42 U.S.C. 262(i)].

In order to lawfully market a drug that is also a biological product, a valid biologics license must be in effect [42 U.S.C. 262(a)]. Such licenses are issued only after a demonstration that the product is safe, pure, and potent. While in the development stage, such products may be distributed for clinical use in humans only if the sponsor has an investigational new drug (IND) application in effect as specified by FDA regulations [21 U.S.C. 355(i); 42 U.S.C. 262(a)(3);21 CFR 601.21; 21 CFR Part 312].

We direct your attention to the FDA's comprehensive regenerative medicine policy framework for HCT/Ps, which is intended to spur innovation and efficient access to safe and effective regenerative medicine products. The policy framework is outlined in a suite of four guidance documents available on the FDA's website at https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/framework-regulation-regenerative-medicine-products.

Manufacturers and health care professionals who have any uncertainty regarding the regulatory status of their products are encouraged to contact the FDA to obtain a recommendation or decision regarding the classification of an HCT/P. For more information in this regard, or to obtain further information about IND requirements for biological products, please see pages 23 and 24 of the guidance entitled, "Regulatory Considerations for Human Cells, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use" at the link to FDA's webpage provided above.

We note that your website also lists exosomes as "being used in conjuction with Regenerative Medicine therapy" at The Regen Center to treat numerous serious diseases and conditions. Please be advised that, as a general matter, exosomes for clinical use in humans are also regulated as drugs and biological products under section 351 of the PHS Act and the FD&C Act and are subject to premarket review and approval requirements described above. For more information, please see FDA's Public Safety Notification on Exosome Products, at https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/public-safety-notification-exosome-products.

This letter addresses certain issues regarding your products and is not intended to be an all-inclusive review. You and your firm are responsible for ensuring that all your products fully comply with the FD&C Act and PHS Act and all applicable regulations. We request a written response within 30 days of your receipt of this letter. Your response should be sent to me at the following address: U.S. Food and Drug Administration, Center for Biologics Evaluation and Research, 10903 New Hampshire

Avenue, Bldg. 71, Silver Spring, MD 20993. In addition, you may also submit an electronic copy of your response to CBERDCMRecommendations@fda.hhs.gov. If you have any questions regarding this letter, please contact the Division of Case Management, CBER at (240) 402-9155. Please be advised that only written communications are considered official.

Sincerely,

Mary A. Malarkey
Director
Office of Compliance and Biologics Quality
Center for Biologics Evaluation and Research